IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Stephen James FIELD et al.	)	
Serial No:	10/803,882	)	Art Unit: 3737
Filed:	March 19, 2004	)	Examiner: Roy, Baisakhi
For:	MEDICAL DEVICES	)	Attorney Docket: 0119/0034

FEE AUTHORIZATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached herewith is Credit Card Payment form PTO-2038 authorizing the charge of $540.00 for the filing of the accompanying Appeal Brief for the above-identified Application.

The Commissioner is hereby authorized to debit funds from Deposit Account No. 50-0501 if the amount noted above is insufficient. A duplicate copy of this letter is attached.

Respectfully submitted,

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Date: Dec. 9, 2008

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APPEAL BRIEF

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REAL PARTY IN INTEREST

The real party in interest of the subject application is Smiths Group PLC to whom the inventors assigned the invention per an Assignment recorded on March 19, 2004 at Reel 015122, Frame 0213 at the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

Co-pending application No. 10/196,151 is believed to be related to the instant case and is on appeal.

TABLE OF AUTHORITIES

STATUS OF CLAIMS

Claims 1 and 3-18 are pending in this application and are being appealed. The being appealed claims are reproduced in the Claims Appendix.

STATUS OF AMENDMENTS

No amendment was filed in response to the Office Action dated September 15, 2008 finally rejecting the claims.[1]

[1] The examiner failed to mark the "Final" box 2a) in the Office Action Summary sheet. However, on page 4, the Office Action of September 15, 2008 was deemed to be a final rejection.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The instant invention relates to a catheter that is formed of two extruded layers in a first embodiment and three extruded layers in a second embodiment. For the two extruded layers, the outer thicker layer forms the main structure of the catheter and is of a bubble-filled material with high ultrasound reflectivity. The inner layer does not have any bubbles and is thinner. The purpose of the inner layer is to provide a smooth inner passage to the catheter so as to make it as atraumatic as possible for embryos, in the case of a catheter that is used as an embryo transfer catheter. Without this inner layer, the inner surface of the catheter would be interrupted by the occasional bubble which breaks to the surface so that the inner passageway of the catheter would not be as smooth.

In particular, independent claim 1 relates to a medical device (1) that comprises an elongate portion of plastics material that is extruded with at least a first inner layer (12) of a plastics material and a second layer (13) of a plastics material on an outside of the inner layer. One of the layers is substantially free of gas bubbles, and the other of the layers provides a main substrate of the device and is extruded to include gas bubble dispersed within the material to increase the visibility of the device under ultrasound imaging. The layer substantially free of gas bubbles is thinner than the layer that has the gas bubbles so that the layer containing the gas bubbles is covered at a surface by the thinner of the layers. [Figs. 2 and 3; page 4, lines 7-13]

Claim 3 depends from claim 1 and defines that the layer that is substantially free of gas bubbles is the inner layer (12). [Fig. 2; page 7, lines 7-13]

Claim 4 depends from claim 1 and defines the second layer (13) to provide the outer surface of the device. [Fig. 2]

Claim 5 depends from claim 1 and requires that the device further includes a third layer (116) on an outside of the second layer (113). [Figs. 5 and 6; page 6, lines 7-11]

Claims 6 depends from claim 5 and defines the second layer (113) to contain gas bubbles, and the first and third layers (112, 116) are substantially free of gas bubbles. [Figs. 5 and 6; page 6, lines 7-11]

Claim 7 depends from claim 1 and defines the bubbles being in a region extending around the entire circumference of the device. [Page 2, lines 21-22; page 4, lines 15-16]

Claim 8 depends from claim 1 and defines the bubbles to extend in a continuous region along the length of the device. [Page 4, lines 15-16]

Claim 13 depends from claim 1 and defines the device as a catheter having a bore extending along its length. [Page 4, lines 3-6]

Claim 14 depends from claim 13 and defines the inner layer to have an inner surface providing the bore of the catheter. [Page 4, lines 7-9]

Claim 15 depends from claim 13 and defines the plastics material to be transparent to the eye and the density of the bubbles being such as to permit the material within the catheter to be viewed by the eye. [Page 6, line 20 to page 7, line 3]

Independent claim 16 recites a catheter that comprises an elongate shaft (1) of plastics material extruded with an inner layer (12) and an outer layer (13) on the outside of the inner layer. The inner layer is substantially free of gas bubbles, whereas the outer layer that provides a main substrate of the catheter is extruded to include gas bubbles dispersed therein to increase the visibility of the catheter under ultrasound imaging. The outer layer is thicker than the inner layer such that the inner surface of the outer layer is covered by the inner layer. [Figs. 2 and 3; page 4, lines 7 to page 5, line 2]

Independent claim 17 recites an embryo transfer catheter that comprises an elongate shaft (1) of transparent plastics material. The shaft is extruded with an inner layer (12) and an outer layer (13) on the outside of the inner layer. The inner layer is substantially free of gas bubbles such that the inner surface of the outer layer is covered by the inner layer, with the outer layer providing the main substrate of the catheter and including gas bubbles dispersed therewithin to increase the visibility of the device in the ultrasound imaging. The density of the bubbles is insufficient to prevent visualization of the embryo in the catheter. The outer layer is thicker than the inner layer. [Figs. 2 and 3; page 6, line 20 to page 7, line 3]

Independent claim 18 recites a catheter that comprises an elongate shaft (1) of plastics material. The shaft is extruded with three layers each of plastics material including an inner layer (112), an outer layer (116) and a middle layer (113) between the inner and the outer layers. The inner and outer layers are substantially free of gas bubbles such that the inner and outer surfaces of the middle layer are covered by the inner and outer layers respectively. The middle layer provides a main substrate of the catheter and is extruded to include gas bubbles dispersed therewithin to increase the visibility of the device under ultrasound imaging. The inner and outer layers are thinner than the middle layer. [Figs. 5 and 6; page 6, lines 7-13]

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1 and 3-18 are unpatentable under 35 U.S. C. 103(a) as being obvious over Rammler (US 5,327,891) and Sarkis et al. (US 5,921,933) in combination with Mills (US 6,723,052)?

ARGUMENT

As discussed above in the Summary of the Invention section, each of independent claims 1, 16, 17 and 18 requires at minimum an elongate portion of plastics material that is extruded with a first layer and a second layer, with one of the layers being substantially free of gas bubbles and the other layer includes gas bubbles dispersed within the material to increase the visibility of the device under ultrasound imaging. Independent claim 1 specifically requires that the layer substantially free of the gas bubbles is substantially thinner than the layer that has the gas bubbles such that the layer containing the gas bubbles is covered at a surface by the thinner layer. Independent claim 16 is directed to a catheter and requires that the gas bubbles dispersed outer layer of the shaft of the catheter be thicker than the inner layer which does not have any gas bubbles and that the inner surface of the outer layer be covered by the inner layer. Independent claim 17 is directed to an embryo transfer catheter that further requires that the density of the bubbles is insufficient to prevent the visualization of an embryo in the catheter. Independent claim 18 is directed to a catheter that has three layers, with the gas bubbles dispersed middle layer sandwiched by the non-gas bubbles inner and outer layers.

Rammler (US 5,327,891) discloses a catheter 12 that has attached thereto at least two vane like ducts or channels that house microbubbles (col. 2, lines 20-26). These vanes extend continuously along substantially the entire length of the catheter and are fitted into corresponding grooves of a track 24, for insertion into the blood vessel of a patient (col. 5, lines 36-41). The microbubbles are introduced into the channels of the vanes by using syringes or other transferring means or mixed with polymer prior to the extension of the extrusion for making the vanes (col. 3, lines 49-52). The microbubble medium may also be introduced to a vane by opening the vane, and the vane also serves as a cushion when it makes contact with the wall of the blood vessel (col. 4, lines 6-11). Rammler is therefore quite different from the arrangement of the present invention where the bubbles are incorporated into the plastics material itself for forming the structure of the device, namely by requiring two different layers only one of which contains the gas bubbles.

Sarkis (US 5,921,933) describes a medical device having a coating or other material containing nanometer sized particles of sonically reflective materials. The reflective particles may be mixed with a polymer that is added as a part of a medical device. In the

various examples shown in Figs. 4-9, a part of each of those devices is filled with the reflective particles mixed material. There is no suggestion in Sarkis that gas bubbles be used in place of the particles, as required in the claims of the present invention. It should be noted that in many medical applications, it is preferable to avoid including particle materials, such as the Sarkis reflective materials. This is because by incorporating the particles into a medical device means the introduction of the risk of potential incompatibility with the body and the risk that the particles will become detached at the surface. Gas bubbles avoid these problems.

Mills (US 6,723,052) discloses an implantable radio therapy device that is arranged to be visible under ultrasound by the incorporation of echogenic surfaces. This is done by adding parabolic surface 3 to a sealed chamber 5 of the device, as shown in Fig. 1. The radioactive source 4 that is used for treating the patient is stored in the sealed chamber 5. Mills defines the parabolic surface as a surface that provides multiple angles of reflectants such that the ultrasonic signal is reflected back to the transducer incorporated into the ultrasonic probe (col. 5, lines 55-62). Mills further discloses that the body chamber 5 may comprise "voids, bubbles or channels filled with gas such as air or nitrogen" (col. 6, lines 36-39). Thus, even though Mills mentions the use of bubbles, it is quite clear that it is the parabolic echogenic surface 3 of the sealed chamber of the device that provides the main reflectivity of the device. Indeed, the chamber of the Mills device is totally enclosed, and necessarily so, insofar as the chamber has to contain the radioisotope needed to treat a particular area of the patient. Mills therefore fails to suggest a device that has extruded layers, with one of those layers containing bubbles and the other free of bubbles, or that one layer is thicker than the other. Mills does not disclose a catheter.

None of Rammler, Sarkis or Mills discloses an extruded catheter having at least two layers, one of which having gas bubbles, while the other does not, and one layer being thicker than the other. This is particularly true of claims 16-18 which specifically recite a catheter that allows passage of a fluid therealong. Furthermore, none of the cited prior art documents discloses an embryo transfer catheter that allows the embryo be viewed as it passes through the catheter, per recited in claim 17. Nor do the cited prior art references suggest a catheter that has three layers, with a gas bubbled middle layer sandwiched by non-gas bubbled inner and outer layers, per recited in claim 18.

In Friskit, Inc. v. Realnetworks, Inc., D.Ct. N.D. Cal., 499 F.Supp.2d 1145, 1149 (2007), the court succinctly sets forth what is required to determine whether a claim is obvious under the KSR holding by the Supreme Court as follows:

> Two principles from the Supreme Court's recent opinion in KSR Int'l Co. v. Teleflex Inc. guide the analysis of whether sufficient difference exists between the prior art and Friskit's claims to render the patents nonobvious. First, "[w]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." KSR Int'l Co. v. Teleflex Inc., __ U.S. __, 127 S.Ct. 1727, 1740, 167 L.Ed.2d 705 (2007) (quoting Sakraida v. Ag Pro. Inc. 425 U.S. 273, 282, 96 S.Ct. 1532, 47 L.Ed.2d 784 (1976)). Second, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product ... of ordinary skill and common sense."

Guided by the KSR analyses, it is clear that the claims at issue recite elements that are not old elements that are simply rearranged to perform the same functions, as none of the cited prior art documents comes close to disclosing an extruded catheter that has two layers, with one of the layers having gas bubbles while the other does not, and that one layer is thicker than the other. Therefore, there are sufficient differences that exist between the claimed subject matter and the cited prior art documents for the claims of the present invention to pass muster under the first KSR analysis as set forth by the court.

For the second KSR analysis, as evidenced by the many references cited in Rammler, Sarkis and Mills, there have been myriad of unidentified and unpredictable attempts at solutions for increasing the visibility of medical-surgical devices under ultrasound. Notwithstanding all those earlier references, Rammler, Sarkis and Mills each disclose different enhanced visibility devices. To wit, Rammler discloses a catheter that is mounted on a catheter track for insertion into a blood vessel of a patient, Sarkis discloses an echogenic coated biopsy needle, and Mills discloses a brachytherapy device that has a radioisotope encased in a sealed chamber that has a parabolic echogenic

surface. Thus, there does not appear to be any "finite number of identified, predictable solutions" that would have led a person of ordinary skill to come up with the present invention.

Accordingly, based on the KSR obviousness analyses noted above, there are sufficient differences between the cited prior art and the present invention to render the claims of the present application patentable over the cited prior art.

Appellants further respectfully submit that the cited documents, rather than combinable as asserted by the examiner, actually teach away from the claimed invention, when viewed by a person skilled in the art.

In In re Icon Health and Fitness, Inc., 496 F.3d 1374, 1381 (CAFC 2007), the court held:

> "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553 (Fed.Cir. 1994); see KSR, 127 S.Ct. at 1739-40 (explaining that when the prior art teaches away from a combination, that combination is more likely to be nonobvious). Additionally, a reference may teach away from a use when that use would render the result inoperable. McGinley v. Franklin Sports, Inc. F.3d 1339, 1354 (Fed.Cir. 2001).

In combining Sarkis with Rammler, the examiner asserts that Rammler is cited in Sarkis and therefore "... Sarkis would evidence the equivalence of bubble mixing into the polymers being extruded into the various catheter wall components of the latter as they are variously thickness apportioned ..." (page 3 of the Office Action).

Sarkis does reference Rammler, by stating that Rammler teaches the introduction of micro-bubbles into polymers to provide echogenic catheter components. Yet a more accurate picture of what Sarkis suggests – with his citation of Rammler, along with the other references cited in his Background of the Invention section -- is that Sarkis points to

a different way of enhancing the echogenicity of a medical device. This is evidenced by the following statements Sarkis made in his Background of the Invention section: "A variety of approaches have been used to enhance ultrasonic imaging of devices by increasing the acoustic reflection coefficient of the devices (col. 1, lines 16-18); "A variety of mechanisms for enhancing the ultrasound image of a portion of a medical instrument are also disclosed in [the Bosley patents]..." (col. 1, lines 21-23). Sarkis further went on to disclose that a number of patents "disclose catheters and other devices provided with echogenic surfaces including spherical indentations or projections ..." (col. 1, lines 26-28), before discussing the use of micro-bubbles in Rammler. After reciting the various approaches and mechanisms including Rammler, Sarkis finally went on to state, at his Summary of the Invention section, that his invention would enhance ultrasound visibility "by virtue of incorporation of an echogenic material" (col. 1, lines 40-42), which he describes as " by incorporating nanometer sized particles of sonically reflective materials" as a coating or as part of a self-curing polymer (Col. 1, lines 42-43).

Thus, on reading Sarkis, a person of ordinary skill would more likely than not think of Sarkis as teaching a method of enhancing ultrasound visibility in a way that is totally different from the earlier references Sarkis described, including Rammler. This is self evident insofar as bubbles and nanometer particles are different materials, and Sarkis specifically introduces the use of nanometer particles despite of his knowledge of bubbles. Thus, if anything, Sarkis would lead a person of ordinary skill to look at the use of nanometer sized reflective particles, instead of bubbles for enhancing echogenic visibility on a medical device.

Sarkis is cited by Mills in the latter's Background of the Invention section. After discussing Sarkis (col. 2, lines 14-16), Mills states, with reference to the discussed background references, that "each of these advancements in the field of echogenic imaging contains limitations" (col. 2, lines 21-22). From there Mills describes his device to have a chamber of parabolic surfaces.

Thus, when a person of ordinary skill has placed in front of him Rammler, Sarkis and Mills, with Sarkis referencing Rammler and Mills referencing Sarkis, with Sarkis saying that instead of gas bubbles, nanometer sized reflective particles should be used to increase echogenity, and with Mills stating that the way to increase echogenity is to have parabolic surfaces at an enclosed chamber, it is hard-pressed to see how a person of ordinary skill

in the art would have combined those references as asserted by the examiner, particularly when Sarkis teaches away from Rammler and Mills teaches away from Sarkis. By their respective teachings, it is more likely that Rammler, Sarkis and Mills would point a person of ordinary skill to different directions for increasing the echogenic visibility of a medical device.

Moreover, even were Rammler, Sarkis and Mills combined as suggested by the examiner, the fact remains that there is no suggestion by any of those references of an extruded catheter that has at least two layers, one being thicker than the other and one having gas bubbles while the other does not. There is also no suggestion in any of those cited documents of the embryo catheter as recited in claim 17 that requires that the embryo be visualized in the catheter, or the three layered catheter of claim 18.

Accordingly, Appellants submit that the present invention, as defined by the being appealed claims, is nonobvious over the cited prior art references.

It is further believed that there is no suggestion in any of the cited documents of the subject matter recited in the dependent claims 3-8 and 13-15 discussed in the Summary of the Claimed Subject Matter section, and which patentabilies are requested to be adjudged separately.

For the reasons set forth above, Appellants submit that all of the independent claims, and the claims dependent therefrom, in the present application are patentably distinguishable over the cited prior art. Accordingly, the Board is respectfully requested to reverse the examiner's rejection.

Respectfully submitted,

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Date: Dec 9, 2008

CLAIMS APPENDIX

1. A medical device comprising an elongate portion of plastics material, the portion being extruded with at least a first, inner layer of a plastics material and a second layer of a plastics material on an outside of the inner layer, wherein one of said layers is substantially free of gas bubbles, wherein the other of said layers provides a main substrate of the device and is extruded to include gas bubbles dispersed within the material of said other layer to increase the visibility of the device under ultrasound imaging, and wherein said layer substantially free of gas bubbles is thinner than said other layer such that the layer containing gas bubbles is covered at a surface by the thinner of the layers.

2. (Canceled)

3. A device according to Claim 1, wherein said layer substantially free of gas bubbles is said inner layer

4. A device according to Claim 1, wherein said second layer provides an outer surface of the device.

5. A device according to Claim 1, including a third layer on an outside of said second layer.

6. A device according to Claim 5, wherein said second layer contains gas bubbles, and wherein said first and third layers are substantially free of gas bubbles.

7. A device according to Claim 1, wherein the bubbles are in a region extending around the entire circumference of the device.

8. A device according to Claim 1, wherein the bubbles extend in a continuous region along the length of the device.

9. A device according to Claim 1, wherein the gas bubbles have a size in the range 0.1μ to 300μ

10. A device according to Claim 9, wherein the gas bubbles have a size in the range 1μ to 50μ.

11. A device according to Claim 10, wherein the gas bubbles have a size in the range 5μ to 10μ.

12. A device according to Claim 1, wherein the gas bubbles are provided by gas-filled polymer microspheres.

13. A medical device according to Claim 1, wherein the device is a catheter having a bore extending along its length.

14. A catheter according to Claim 13, wherein said inner layer has an inner surface providing the bore of said catheter.

15. A catheter according to Claim 13, wherein said plastics material is transparent to the eye, and wherein the density of bubbles is such as to permit material within the catheter to be viewed by the eye.

16. A catheter comprising an elongate shaft of plastics material, the shaft being extruded with an inner layer of a plastics material and an outer layer of a plastics material on an outside of the inner layer, wherein said inner layer is substantially free of gas bubbles, wherein said outer layer provides a main substrate of the device and is extruded to include gas bubbles dispersed within the plastics material of said outer layer to increase the visibility of the device under ultrasound imaging, and wherein said outer layer is thicker than said inner layer such that the inner surface of the outer layer is covered by the inner layer.

17. An embryo transfer catheter comprising an elongate shaft of transparent plastics material, the shaft being extruded with an inner layer of a plastics material and an outer layer of a plastics material on an outside of the inner layer, wherein said inner layer is substantially free of gas bubbles such that the inner surface of the outer layer is covered by the inner layer, wherein said outer layer provides a main substrate of the catheter and includes gas bubbles dispersed within the plastics material of said outer layer to increase the visibility of the device under ultrasound imaging, wherein the density of bubbles is

insufficient to prevent visualization of an embryo in the catheter, and wherein said outer layer is thicker than said inner layer.

18. A catheter comprising an elongate shaft of plastics material, the shaft being extruded with three layers each of a plastics material, wherein the shaft comprises an inner layer, an outer layer and a middle layer between said inner and outer layers, wherein said inner and outer layers are substantially free of gas bubbles such that the inner and outer surfaces of the middle layer are covered by the inner and outer layers respectively, wherein said middle layer provides a main substrate of the catheter and is extruded to include gas bubbles dispersed within the plastics material of said middle layer to increase the visibility of the device under ultrasound imaging, and wherein said inner and outer layers are thinner than said middle layer.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.